JUN 2 0 2013

510(k) Summary

NAME OF FIRM:	OrthoPediatrics, Corp. 2850 Frontier Drive Warsaw, IN 46582
DATE PREPARED:	June 10, 2013
510(K) CONTACT:	Mark Fox Vice President, Regulatory Affairs Tel: (574) 268-6379
PROPOSED TRADE NAME:	OrthoPediatrics ACL Reconstruction System
DEVICE CLASSIFICATION:	Class II; 21 CFR 888.3040
CLASSIFICATION NAME:	Fastner, Fixation, Nondegradable, Soft Tissue
PRODUCT CODE:	MBI
DEVICE DESCRIPTION:	The OrthoPediatrics ACL Reconstruction System is a two part fixation system for anchoring soft tissue grafts in ACL deficient patients. It is available in diameters of 6mm, 6.5mm, 7mm, 7.5mm, 8mm, 8.5mm, 9mm, & 10mm in order to accommodate differing anatomic requirements. The first system is a screw designed to work in conjunction with a sleeve that has been fitted into the graft tunnel within the bone. Both screw and sleeve components are made entirely of PEEK Optima. The second system consists of a titanium alloy implant intended to hook onto the looped portion of the soft tissue graft and then rest onto the cortex at the end of the graft tunnel.
INDICATIONS FOR USE:	The OrthoPediatrics ACL Reconstruction System is intended for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.
MATERIALS:	Titanium Alloy per ASTM F136 PEEK Optima per ASTM F2026
PREDICATE DEVICES:	EndoButton CL Ultra (Smith & Nephew, K980155) for the loop fixation implant. Arthrex Sheathed Cannulated Interference Screw (Arthrex, K062466) for the screw & sleeve construct.
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics, including the intended use, material, and

general design, and sizes of the device are the same as, or similar to, the predicate devices. The OrthoPediatrics ACL Reconstruction System possesses a modified technological characteristic in that the femoral component utilizes a sleeve construct in order to prevent off axis screw tracking.

PERFORMANCE DATA:

Static pull out testing as well as dynamic cyclic loading were utilized in order to characterize the mechanical properties of the OrthoPediatrics ACL Reconstruction System. The results demonstrated that the OrthoPediatrics ACL Reconstruction System is substantially equivalent to predicate device performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

OrthoPediatrics, Corporation
% Mr. Mark Fox
Vice President, Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K130217
Trade/Device Name: OrthoPediatrics ACL Reconstruction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 15, 2013
Received: May 16, 2013

Dear Mr. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 Indications for Use Statement

510(k) Number: K130217

Device Name: OrthoPediatrics ACL Reconstruction System

Indications for Use:

The OrthoPediatrics ACL Reconstruction System is intended for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.

Prescription Use___X___ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices